

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: STINSON Examiner: UNKNOWN
Serial No.: NEW FILING Art Unit: UNKNOWN
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Filed: HEREWITH Docket: PC10247C
Title: NEUROANEURYSM OCCLUSION AND DELIVERY DEVICE AND
METHOD OF USING SAME

PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

BOX PATENT APPLICATION
Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

Applicant respectfully requests that the following Preliminary Amendment be made of record and considered before the first Office Action on the merits.

IN THE CLAIMS

Please cancel claims 1-32 and add new claims 33-55 as follows:

33. (New) An occlusion device delivery system comprising:
a tubular body including a proximal end, a distal portion, a distal end on the distal portion, and a length between the distal end and the proximal end;
an occlusion device having
two ends,
a length between the ends,
a first diameter which is substantially uniform along the length of the occlusion device prior to delivery and a second diameter which varies along the length of the occlusion device after delivery, and
a lumen therethrough, the tubular body traversing the lumen;

a distal tip disposed on the distal portion of the tubular body, the distal tip including at least a partially bioabsorbable or dissolvable material, wherein the distal tip has a first dimension prior to introduction into a body lumen and a second smaller dimension after the distal tip is disposed within a body lumen.

34. The delivery system of claim 33 wherein the bioabsorbable or dissolvable material is selected from the group comprising poly(vinyl pyrrolidone), methyl cellulose, carboxymethyl cellulose, cellulose derivative, or poly(ethylene oxide), colloidal hemicellulose gelatin, starch, or combinations thereof.

35. The delivery system of claim 33 wherein the distal tip further comprises a lumen.

36. The delivery system of claim 33 wherein the distal tip is made of at least one of a biostable polymer and bioabsorbable or dissolvable composite material, biostable polymer core and bioabsorbable or dissolvable shell, biostable polymer shell and bioabsorbable or dissolvable core, porous biostable polymer matrix filled with a bioabsorbable or dissolvable material, or combinations thereof.

37. The delivery system of claim 33 wherein the distal tip bioabsorbs or dissolves in less than about 15 minutes.

38. The delivery system of claim 33 wherein the distal tip has a first dimension D prior to introduction into a body lumen and is configured to have one or more additional dimensions D' ranging from about 0% to about 80% of the first dimension D after disposed *in vivo*.

39. The delivery system of claim 33 wherein the distal tip is configured to be in a first shape prior to placement in a body lumen and in one or more additional shapes when *in vivo*.

40. The delivery system of claim 33 wherein the distal tip is configured to either bioabsorb or dissolve to one or more smaller profiles, or bioabsorb or dissolve substantially away.

41. The delivery system of claim 33 wherein the distal tip has a substantially smooth transition at an edge of the tubular body.

42. The delivery system of claim 33 wherein the distal tip further comprises a deformable material.

43. The delivery system of claim 33 wherein the distal tip is molded or cast from a non-toxic, biocompatible material.

44. The delivery system of claim 34 wherein the distal tip degrades or bioabsorbs within a range of about 5 to about 10 minutes when *in vivo*.

45. A method of using a delivery device comprising the steps of:
providing a delivery device having a tubular body including a proximal end, distal portion, a distal end on the distal portion, and a length between the distal end and the proximal end, a distal tip disposed on the distal portion of the tubular body, the distal tip including at least one of a dissolvable, bioabsorbable and deformable material, a medical device associated with the distal tip positioned on the distal portion of the tubular body, the body having

two ends,

a length between the ends,

a first diameter which is substantially uniform along the length of the occlusion device prior to delivery and a second diameter which varies along the length of the occlusion device after delivery, and

a lumen therethrough, the tubular body traversing the lumen;

inserting the delivery device into a body lumen;
advancing the delivery device to a desired location within the body lumen;
deploying the medical device in the body lumen;
allowing at least a portion of the distal tip to at least one of deform,
dissolve or bioabsorb to a lower profile; and
withdrawing the tubular body from the body lumen.

46. The method for using a delivery device of claim 45 further comprising the step of:

withdrawing the distal end of the tubular body through at least a portion of the medical device.

47. An occlusion device comprising:

a first set of filaments each of which extends in a configuration along a center line and having a first common direction of winding;

a second set of filaments each of which extends in a configuration along a center line of the occlusion device and having a second common direction of winding;

a structural support system formed by the first set of filaments and the second set of filaments, the structural support system including a proximal end and a distal end, a diameter, and an inside surface and an outside surface; and

at least one thrombogenic treatment including at least one of a coating, fuzz, or fibers disposed on at least a portion of one or more filaments, the thrombogenic treatment adapted to cause thrombosis and vessel occlusion.

48. The occlusion device of claim 47 wherein the structural support system has a diminishing diameter on at least one end.

49. The occlusion device of claim 47 further comprising a member having an outside diameter and an inside diameter.

50. The occlusion device of claim 47 wherein the structural support system has a shape selected from the group comprising cone-like, elliptical, cylindrical, trumpet-like and funnel-like.

51. The occlusion device of claim 49 wherein the member is made of at least one of Elgiloy®, biostable polymer material, or bioabsorbable polymer material.

52. The occlusion device of claim 49 wherein the member is a substantially continuous ring.

53. The occlusion device of claim 47 wherein the thrombogenic treatment substantially encapsulates a plurality of ends of the filaments.

54. The occlusion device of claim 47 wherein the filaments have an average diameter of from about 0.0254 mm to about 0.7 mm.

55. The occlusion device of claim 47 wherein the filaments are selected from the group comprising: 1) a metal with spring characteristic properties including Elgiloy®, 304 stainless steel, 316 stainless steel, or nitinol; 2) a polymer with a generally high Young's Modulus and yield strength including PET or nylon; 3) a bioabsorbable polymer including (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymer materials; and 4) a metal with a generally high ductility and generally low to moderate yield strength including annealed stainless steel, platinum, gold, tungsten, or tantalum.

REMARKS

Applicant respectfully requests submission of the above amendments to this continuation application prior to examination on the merits.

Respectfully submitted,

Date: 5/10/01



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CERTIFICATE UNDER 37 C.F.R. § 1.10:

"Express Mail" mailing label number: EL056549748US

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I hereby certify that this paper or fee is being deposited with the United States Postal Service, "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Brenda House
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